

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12722



2 - LABEL SAMPLE

1. FLAG SURVEILLANCE <input checked="" type="checkbox"/> COMPLIANCE <input type="checkbox"/>				2. TYPE SAMPLE		3. SAMPLE NUMBER 98-694-500	
4. CF NO. 1722141		5. DATE COLLECTED 12/19/97		6. PRODUCT CODE 60CBF21		7. RESP FIRM M	
10. RELATED SPL 98-553-720		11. PC 2		12. COLL NO. 851		13. SPLING DIST DET	
				14. COLL DIST DET		15. PROGRAM ASSIGN CODE 218900	
						16. HOURS 1 2	
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) EPHEDRINE, CAFFEINE & ASPARIN grey hard gelatin capsules packaged in a white plastic bottle with a white plastic flip open cap. Bottle is labeled in part "THERMOGENICS plus PART 1 Complete Fat Management System Nutrients the body used to help INCREASE ENERGY SUPPRESS APPETITE REACTIVATE NATURAL FAT BURNING PROCESS dietary supplement 60 CAPSULES 850 MG EACH *** Ingredients: (Contains only whole mahaung - no added ephedrine.) Active Ingredients: Ephedrine, caffeine and aspirin. In a base of adjunctive nutrients: Ma huang, Bissey Nut, Vitamin C, Siberian Ginseng, ThermoFlax (Powdered Flax Seed Oil), Willow Bark, Cayenne, Wintergreen, Pantothenic Acid, Ginger Root, Zinc, Manganese, Selenium. by Silver Sage P.O. Box 1117 SLC, UT 84020 *** These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. ***".							
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) Collected in conjunction with investigation into the death of [REDACTED] on 12/9/97.						17. MFG CODES (Labels, pkg, shipping containers) "7090170" from bottle neck	
18. MANUFACTURER (Name, address & ZIP) by Alpine Industries, Alpine, UT for Silver Sage Salt Lake City, UT 84020 1-800-842-2742				19. SHIPPER (Name, address & ZIP) unknown		20. DEALER (Name, address, ZIP & telephone) [REDACTED]	
21. SIZE OF LOT FROM WHICH SAMPLED 1 Partial bottle containing 23 capsules				22. EST VALUE unknown		23. RECEIPT ISSUED FDA472 FDA484 NONE Y	
24. DATE SHIPPED & DOC REF unknown							
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) Partial bottle collected from [REDACTED] Staff. Reportedly bottle and its contents were found in the room of the deceased [REDACTED] by his roommate.							
26. HOW PREPARED sample as in block 25 identified as in block 27 and placed in brown paper bag, identified as in block 27 and sealed as in block 28.							
27. COLL IDENT ON PKG AND/OR LABEL "98-694-500 12/19/97 Pjd"				28. COLLECTOR'S IDENTIFICATION ON SEAL "98-694-500 2/19/98 Patsy J. Domingo" see Remark			
29. SAMPLE DELIVERED TO FED-X'd to Carl Reynolds, Director Office of Field Programs HFS-600				30. DATE DELIVERED 02/19/98		31. LAB unknown	
				32. LAB W/SPLIT SAMPLE -----		33. ORIG C/R & RECORDS TO DET-DC	
34. RCDS	a. INVOICE NO. AND DATE N/A			b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavits, etc.) NO. AND DATE N/A			
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE N/A						
35. REMARKS (If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet) Block 28. continued: sample stored in locked locker until sealed. Attached to this CR: FDA-484, Receipt for Samples.							
36. CONSUMER COMPLAINT NO. OR RECALL NO. N/A		37. AMOUNT NC CRED. CD. C V B <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		38. 704(d) SPL YES NO <input type="checkbox"/> <input checked="" type="checkbox"/>		39. COLLECTOR (Typed name and signature) Patsy J. Domingo, Investigator	

FORM FDA 464 (11/85) PREV ED MAY BE USED.

COLLECTION REPORT

COPY: ORIGINAL DPU MONITOR COLLECTOR FISCAL SAMPLE

000002

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. SAMPLE NUMBER

5. FIRM NAME

6. FIRM'S DEA NUMBER

7. FDA'S DEA NUMBER

8. NUMBER AND STREET

9. CITY AND STATE (Include Zip Code)

10. SAMPLES COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374 (c)] and / or Part F, Sub Part 3, Section 356(b) of The Public Health Service Act [42 U.S.C. 263d] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

1 partial bottle Thermobionics plus, lot # 7090170
1 partial bottle Pro Chrome II Chromium 500mg
lot 54243EX APR 99
1 partial bottle Aleve lot 26123251 EXP
APR 00
1 partial bottle, 6 tablets, Rx I buy often
500mg dated 1/29/1996

11. SAMPLES WERE

- ☒ PROVIDED AT NO CHARGE
☐ PURCHASED
☐ BORROWED (To be returned)

12. AMOUNT RECEIVED FOR SAMPLE

- ☐ CASH ☐ BILLED
☐ VOUCHER ☐ CREDIT CARD

13. SIGNATURE (Person receiving payment for sample or person providing sample to FDA at no charge.)

14. COLLECTOR'S NAME (Print or Type)

15. COLLECTOR'S TITLE (Print or Type)

16. COLLECTOR'S SIGNATURE

P. # 12722

1. PRODUCT Therme Genics Plus		2. SAMPLE NO. 7425 (98-694-500)									
3a. SAMPLE CLASSIFICATION <small>(Insert classification code for each PAC No. represented by sample.)</small> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <th style="width: 15%;">CODE</th> <th style="width: 85%;">PAC NO.</th> </tr> <tr> <td style="text-align: center;">4</td> <td>21 R800</td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>		CODE	PAC NO.	4	21 R800					b. LABORATORY CONCLUSIONS Sample consisted of one (1) previously opened bottle of capsules. Analysis for ephedrine alkaloids by LAB 3996. Found: 9.3 mg/g = 7.7 mg / capsule ephedrine. A nonquantifiable trace of pseudoephedrine was also found.	
CODE	PAC NO.										
4	21 R800										
c. NAME AND TITLE Michael S. Liguori, Chemist		d. SIGNATURE 									
4a. DISTRICT CONCLUSIONS <div style="height: 100px; border: 1px solid black;"></div>		e. DATE 6-12-98									
b. NAME AND TITLE (District)		c. SIGNATURE									
d. DATE		e. DATE									

FORM FD 465 (4/78)

PREVIOUS EDITION IS OBSOLETE.

★ U.S. GPO: 1985-461-364/37051

SAMPLE SUMMARY

98 JUN 29 12:25

RECEIVED
 CLINICAL RESEARCH
 & REVIEW/OSN HFS-452

000004



Also Provides Anti-Oxidant Benefits

THERMOGENICS PLUS™ Usage: For health supplementation: Take 1 to 3 daily with meals. Take with 8 to 10 oz. glass of water. Initially start with one capsule and gradually increase to desired level, not to exceed 3 capsules per day (2 early a.m., 1 early p.m.), 5 days per week. To avoid restlessness take prior to 3:00 p.m. THERMOGENICS PLUS™ is part of Silver Sage's *Complete Fat Management™* System and is optimally effective when used with LIPOLYTICS PLUS® and METABOLICS PLUS.®

CAUTIONS: Do not use if you are pregnant or nursing. Use this or any similar product under the supervision of your doctor if you have high blood pressure, a history of cardiovascular or thyroid disease, prostate problems, diabetes, or are using medications for these conditions, or using M.A.O. inhibitors. Reduce or discontinue use if nervousness, tremors, or nausea occur. Do not take this product if you are sensitive to aspirin. **NOT TO BE SOLD TO OR TAKEN BY ANYONE UNDER THE AGE OF 18,** unless under the supervision of a physician. ***These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. Keep out of reach of children.**

77

Ingredients: (Contains only whole mahuang - no added ephedrine.) Active Ingredients: Ephedrine, caffeine and aspirin. In a base of adjunctive nutrients: Ma huang, Bissey Nut, Vitamin C, Siberian Ginseng, ThermoFlax™ (Powdered Flax Seed Oil), Willow Bark, Cayenne, Wintergreen, Pantothenic acid, Ginger Root, Zinc, Manganese, Selenium.

*By Silver
Sage*

P.O. Box 1117 SLC, UT 84020

Phone 1-800-842-2742

Manufactured in the U.S.A.

[bar code]

THERMOGENICS PLUS™ is part of a *Complete Fat Management™* System and is optimally effective when used with:

PART 2 LIPOLYTICS PLUS®

PART 3 METABOLICS PLUS®

FAT BURNER *with* ADRENAL SUPPORT
THERMOGENICS

plus™

PART 1 *Complete Fat Management System*

*Nutrients the body uses to help: **

- INCREASE ENERGY
- SUPPRESS APPETITE
- REACTIVATE NATURAL
FAT BURNING PROCESS

[APRL logo]

dietary supplement

60 CAPSULES • 850 MG EACH

*Verified by [signature] 2-10-98
michele S. Lignard*

ANALYST WORKSHEET		1. PRODUCT ThermoGenics Plus		2. SAMPLE NUMBER 7425(98-694-500)																						
3. SEALS <input type="checkbox"/> NONE <input type="checkbox"/> INTACT <input checked="" type="checkbox"/> BROKEN		4. DATE REC'D 5/13/98		5. RECEIVED FROM [REDACTED]																						
		6. DISTRICT OR LABORATORY SEA-DO																								
7. DESCRIPTION OF SAMPLE One brown paper bag, identified "98-694-500 12/19/97 PJD", official seal "98-553-720 2/19/98 Patsy ** Domingo" (middle initial is illegible; seal is broken; seal is not as described on C/R), containing one open bottle of product, id'd "98-694-500 12/19/97 PJD" (23 capsules remaining). Received at room temperature.																										
8. NET CONTENTS <input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED		DECLARED/UNIT AMOUNT FOUND % OF DECLARED		9. LABELING <input checked="" type="checkbox"/> ORIGINALS SUBMITTED <input checked="" type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE																						
10. SUMMARY OF ANALYSIS container : opaque white plastic bottle, 106mm high x 51mm diameter, with snap-on lid, 39mm labeling : commercially printed paper label glued to bottle code : "7090170" stamped on bottle product : opaque white conventionally shaped 2-piece hard gelatin capsules, capsule standard size 00, containing brown herbal powder Analysis : for ephedrine alkaloids by LIB 3996 Results : <table border="0"> <tr> <td></td> <td>mg/g</td> <td>mg/capsule</td> </tr> <tr> <td>Norephedrine</td> <td>none det</td> <td>none det</td> </tr> <tr> <td>Ephedrine</td> <td>9.3</td> <td>7.7</td> </tr> <tr> <td>Pseudoephedrine</td> <td>trace</td> <td>trace</td> </tr> <tr> <td>Methylephedrine</td> <td>none det</td> <td>none det</td> </tr> <tr> <td>Methylpseudoephedrine</td> <td>none det</td> <td>none det</td> </tr> <tr> <td>Total alkaloid</td> <td>9.3mg/g</td> <td>7.7mg/capsule</td> </tr> </table>							mg/g	mg/capsule	Norephedrine	none det	none det	Ephedrine	9.3	7.7	Pseudoephedrine	trace	trace	Methylephedrine	none det	none det	Methylpseudoephedrine	none det	none det	Total alkaloid	9.3mg/g	7.7mg/capsule
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Total alkaloid	9.3mg/g	7.7mg/capsule																								
11. RESERVE SAMPLE In original paper bag, officially sealed "7425 6/11/98 JLBussey", one open bottle of product, 11 capsules remaining, additionally id'd "5/13/98 JLBussey" and one heat-sealed plastic bag of remaining composite id'd "98694500 (7425) 5/13/98 JLBussey". Returned to sample custodian.																										
12. a. ANALYST SIGNATURE (<input type="checkbox"/> BROKE SEAL) JLBussey		13. WORK SHEET CHECK		a. BY [Signature]																						
b.				b. DATE 6-12-98																						
c.		14. DATE REPORTED 11 June 98																								

1. FLAG SURVEILLANCE <input checked="" type="checkbox"/> COMPLIANCE <input type="checkbox"/>				2. TYPE SAMPLE		3. SAMPLE NUMBER 98-553-720	
4. CF NO. 2521289		5. DATE COLLECTED 12/19/97		6. PRODUCT CODE 54BBH15		7. RESP FIRM M	
10. RELATED SPL 98-694-500		11. PC 2		12. COLL NO. 851		13. SPLING DIST DET	
				14. COLL DIST DET		15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) CHROMIUM A brown soft gelatin capsule packaged in a black plastic bottle with a gold screw on cap. Bottle is labeled in part "***PRO CHROME II CHROMIUM 500 mcg ***30 SOFTGEL CAPSULES *** EACH CAPSULE CONTAINS Chromium Picolinate 4.39 mg ***Distributed by: General Nutrition Corporation Pittsburgh, PA 15222 USA 54243EX APR 99 ***".	
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) Collected in conjunction with investigation of the death of [REDACTED] on 12/9/97.						17. MFG CODES (Labels, pkg. shipping containers) "54243 EX APR99" from product label	
18. MANUFACTURER (Name, address & ZIP) Distributed by: General Nutrition Corp. Pittsburg, PA 15222				19. SHIPPER (Name, address & ZIP) Unknown		20. DEALER (Name, address, ZIP & telephone) [REDACTED]	
21. SIZE OF LOT FROM WHICH SAMPLED 1 partial bottle containing 7 capsules				22. EST VALUE unknown		23. RECEIPT ISSUED FDA472 FDA484 NONE Y	
24. DATE SHIPPED & DOC REF N/A							
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) partial bottle collected from [REDACTED] Staff. Reportedly, bottle and its contents were found in the room of the deceased [REDACTED] by his roommate.							
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	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE N/a						
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. SAMPLE NUMBER

5. FIRM NAME

6. FIRM'S DEA NUMBER

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(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

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- 1 partial bottle Pro Chrome II Chromium 500mcg
lot 54243EX APR 99
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apr 00
- 1 partial bottle, 6 tablets, Rx I bupropion.
800mg dated 1/29/1996

11. SAMPLES WERE

- ☒ PROVIDED AT NO CHARGE
- ☐ PURCHASED
- ☐ BORROWED (To be returned)

12. AMOUNT RECEIVED FOR SAMPLE

- ☐ CASH ☐ BILLED
- ☐ VOUCHER ☐ CREDIT CARD

13. SIGNATURE (Person receiving payment for sample or person providing sample to FDA at no charge.)

14. COLLECTOR'S NAME (Print or Type)

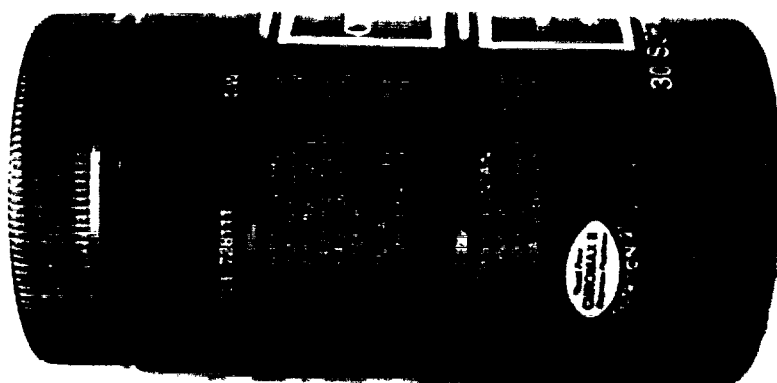
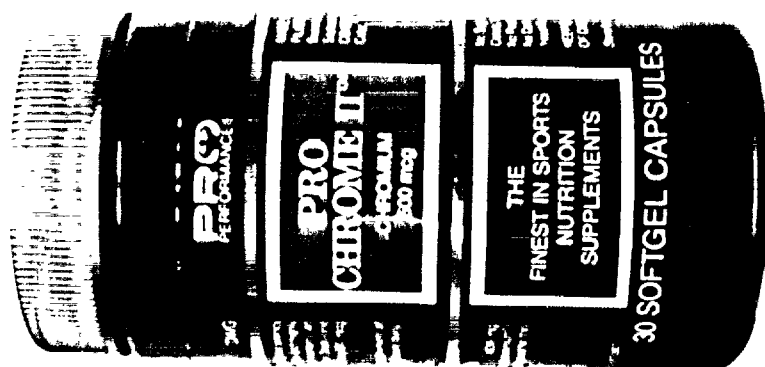
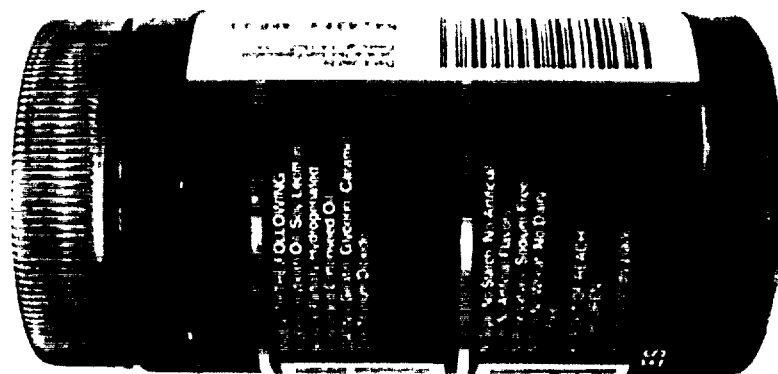
Patsy J. Domingo

15. COLLECTOR'S TITLE (Print or Type)

Investigator

16. COLLECTOR'S SIGNATURE

Patsy J. Domingo



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